CHAPTER 4

HUMAN SUBJECTS DETERMINATION CHECKLIST

This checklist should be used to determine whether human subjects are involved in the research project and whether the research is exempt under the Department of Commerce regulations (see 15 C.F.R. Part 27) for the protection of human subjects. A proposal may contain more than one research activity involving human subjects, and each activity may require a different level of review. This checklist should be used for each potential use of human subjects. NIST and the Technology Innovation Program (TIP or "the Program") reserve the right to make an independent determination of whether your research involves human subjects. If NIST or the Program determines that your research project involves human subjects, you will be required to provide additional information for review and approval. A timeline for the submission of required documents can be found in Appendix 5 of the booklet titled TIP Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects.

A copy of this appendix may also be found at **http://www.nist.gov/tip/helpful.html**.

1. Is there an intervention or an interaction with a living person that would not be occurring or would be occurring in some other fashion but for this research? Examples: videotaping people, observing children using software, surveying manufacturing personnel during a pilot test of new equipment, gathering tissue or cells from living human donors.

   ☐ Yes—Human subjects are involved. Go to question 3.

   ☐ No—Go to question 2.

2. a. Will data/information/specimens previously collected originally from people or about people be used in this research? Examples: broadcast video, Web-use logs, medical information, cells or tissues, survey questions.

   ☐ Yes—Identifiable human subjects may be involved. Go to question 2.b.

   ☐ No—Go to question 6. It appears that human subjects may not be involved in the project. However, an exemption determination may be required if it is determined that human subjects are involved. Please review question 3 for additional information about research that may require either a determination of whether the activity is not considered a use of human subjects in research under the regulation or an exemption determination.

   b. Does that information contain private information in a form in which the identity of the subject is or may readily be ascertained from the information? Examples: medical records, donor name or address, sales transaction records.

   ☐ Yes—Identifiable human subjects are involved. Go to question 3 to see if an exemption may apply. If you know that an exemption does not apply, proceed to question 5.

   ☐ No—Go to question 3. The research may not be within the scope of 15 C.F.R. Part 27; however, it may require an exemption determination to be made due to the use of data, recordings, or specimens that could be linked to humans without appropriate safeguards.

3. Do you think the research task may either not be within the scope of 15 C.F.R. Part 27 or qualify for an exemption under 15 C.F.R. § 27.101(b)? The following questions will help you evaluate whether to request an exemption determination by NIST and the Program or to provide documentation that the research may not be within the scope of 15 C.F.R. Part 27:

   a. Will the research task involving human subjects use only existing data, recordings (audio or visual), or specimens? Examples: patient records, a company's customer data, Web-use logs, cells, or tissue.

      ☐ Yes—Go to question 3.d.

      ☐ No—Go to question 3.b.

   b. Will the research task involve only normal educational practices such as instructional strategies or comparison of instructional techniques, curricula, or classroom management methods? Examples: observation of student-teacher or student-computer interactions, video taping instructional approaches.

      ☐ Yes—Go to question 3.d.

      ☐ No—Go to question 3.c.

   c. Will the research task involve only educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior? Examples: broadcast video, software usage testing, recordings from security cameras.

      ☐ Yes—Go to question 3.e.

      ☐ No—Go to question 5. This research is probably not exempt and will require Institutional Review Board (IRB) review and approval.

   d. Do any of the data, recordings, specimens, or practices involve prisoners? Examples: testing educational software with prisoners, videotaping or surveying prisoners or detainees under the authority of a law enforcement entity.

      ☐ Yes—Go to question 5. This research is probably not exempt and will require IRB review and approval.

      ☐ No—Go to question 3.f.

   e. Do the procedures or observations of public behavior involve prisoners or children?

      ☐ Yes—Go to question 5. This research is probably not exempt and will require Institutional Review Board (IRB) review and approval.

      ☐ No—Go to question 3.h.

   f. Are the data, recordings (audio or visual), or specimens publicly available?
      NOTE: Publicly available may include items for sale, items that are freely available to the public, or items that reside in the public domain. Examples: customer data sets, catalog orders of cells or tissues, donations of pathological specimens, shareware.

      ☐ Yes—Go to question 4. This research may be exempt under 15 C.F.R. § 27.101(b).

☐ No—Go to question 3.g.

g. Will the data, recordings (audio or visual), or specimens be stripped of all identifiable information that could be linked to a human subject prior to being received by the investigator?

☐ Yes—Go to question 4. This research may not be within the scope of 15 C.F.R. Part 27, or this research may be exempt under 15 C.F.R. § 27.101(b).

☐ No—Go to question 3.h.

h. Will information be recorded by the investigator in such a way that it can be linked to the human subject? Examples: Web-use logs tied to e-mail addresses, patient records, or specimens that include patient identifiers.

☐ Yes—Go to question 5. This research is probably not exempt and will need an IRB review.

☐ No—Go to question 4. This research may be exempt under 15 C.F.R. § 27.101(b).

4. An exemption under 15 C.F.R. § 27.101(b) may apply to the task, or the task may not be within the scope of 15 C.F.R. Part 27. In order to complete the necessary requirements for research considered exempt under 15 C.F.R § 27.101(b), review the TIP Program Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects. A copy of that booklet can be obtained on the TIP Web site at http://www.nist.gov/tip/helpful.html or by calling 1-888-TIP-NIST (1-888-847-6478) and requesting a copy. Complete Appendix 3 and/or Appendix 4 in the booklet as required and submit with your proposal or your request to add the research activity to an ongoing project. During the review of a proposal by the Evaluation Panel you may be asked for additional information. However, additional documentation to reach a final determination may also be requested after the proposal is funded.

5. An exemption probably does not apply to the proposed research, however further documentation may still be required. Review the TIP Program Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects. A copy of that booklet can be obtained on the TIP Web site at http://www.nist.gov/tip/helpful.html or by calling 1-888-TIP-NIST (1-888-847-6478) and requesting a copy. See Appendix 5 in the booklet for the required documentation list for your proposal or to add the research activity to an ongoing project. During the review of a proposal by the Evaluation Panel you may be asked for additional information. However, additional documentation to reach a final determination may also be requested after the proposal is funded.

6. It appears that human subjects are not involved in this project. This checklist is only a tool for general guidance and does not constitute a final legal opinion from NIST on whether or not human subjects are involved, or whether or not an exemption determination under the regulations is needed. If upon NIST and Program review of the proposed research it is determined that additional documentation is needed to reach a preliminary determination, you will be asked to provide the additional documentation. During the review of a proposal by the Evaluation Panel you may be asked for additional information. However, additional documentation to reach a final determination may also be requested after the proposal is funded.